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Daniela Verthelyi, MD/PhD

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Education:

1988 MD: University of Buenos Aires, Argentina.

1996 PhD; Virginia-Maryland Regional College of Veterinary Medicine, Virginia Tech, Virginia.

Other courses:

2004 Basic Drug law. CDER.

2004 Proteins and Peptides: Scientific Foundation for Reviewers.
 2005 Antisense and oligonucleotides Therapeutic Symposium

2006 Glycomics and Sweet pharmaceuticals- Advances in glycobiology

Professional Appointments:

Lab Chief, 2008-present

Laboratory of Immunology, Division of Therapeutic Proteins, Office of Biotechnology products, Center for Drug Research and Evaluation,

Food and Drug Administration,

Bethesda, MD.

Senior Investigator, Apr-Dec. 2007

Laboratory of Immunology,
Division of Therapeutic Proteins, OBP/CDER/FDA

Bethesda, MD.

Senior Staff Fellow 2002-2007

Laboratory of Immunology,
Division of Therapeutic Proteins, OBP/CDER/FDA
Rethesda, MD.

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Senior Staff Fellow 1997-2002 Laboratory of Retroviral Immunology,

Division of Viral Products, CBER/ FDA
Bethesda. MD

Oak Ridge Fellow 1996-1997

Laboratory of Retroviral Immunology, Division of Viral Products, CBER/ FDA; Bethesda, MD.

General practitioner 1988-1989

Emergency Medicine, Hospital Municipal de Pilar, Buenos Aires, Argentina.

Research Fellow 1986-1989

Dept. de Obstetrics y Gynecology Hospital Municipal Sarda, Buenos Aires, Argentina.

Description of current duties:

- Principal investigator of a research program focused on the identification and characterization of modulators of the innate immune response as they relate to potential therapies for infection with agents of bioterrorism and emerging pathogens.
- · Train and supervise 2 postdoctoral fellows, and a technician.
- Provide expert advice for policy and guidance development, as a member of the CDER/CBER Biotechnology CTWG group, CBER/CDER counterbioterrorism research working group, anthrax immune products strategy working group, Interagency Coordinating Committee on the Validation of Alternative Methods. Committee for Advanced Scientific Education.
- Reviewer of multiple investigational new drug applications (INDs) and biologics license applications (BLAs) targeting infectious agents, cancer and autoimmune diseases. FDA-wide consult for product immunogenicityassociated adverse events

Grants and Awards (Selected, full list available upon request):

- Assessment of the effects of product impurities that stimulate toll like receptors on product immunogenicity. CDER's Regulatory Science and Review Enhancement program, February 2006.
- Effect of sex hormones on the immune response to CpG ODN Office of Women's Health Grant. March. 2002

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 Optimization of immunoprotective agents to Induce Protective Immunity against Biowarfare Pathogens. Intramural Counter Bioterrorism Initiative. February, 2002.

- CBER Special accomplishment award "for designing CpG ODN that stimulate human T cells and developing assays to detect that stimulation". 1998
- National Institute of Environmental Health Sciences. Travel Award, 1998.
- American Society for Reproductive Immunology, Travel Award, 1996
- Lupus Foundation of America. Gina Finzi Memorial Fellowship award. 1995.
- Sigma Xi Research Fellowship Award. 1995.
- Virginia Polytechnic Institute and State University. Graduate Research Development Program Award. 1994, 1995.
- Virginia-Maryland College of Veterinary Medicine, Dean's list, 1990-1994.
- University of Buenos Aires, Competitive Research Fellowship. 1985, 1986, 1987.

Professional Societies Memberships and Activities:

- American Association of Immunology; International Society for interferon and Cytokine Research
- NIH Cytokine Interest Group (Steering committee since 2002, Treasurer 2004-2007, Co- Chair 2006-2007, Chair 2007-2008).
 - Symposium on Cytokines in Innate Immunity, September 2002 (Organizer and Chair).
 - Symposium on Type I Interferons, April, 2005 (Organizer and Chair).
- FDA Counter Terrorism Research Working Group Seminar series. 2003-2005 (Co-Chair).
- Symposium on Medical Countermeasures and Innate Immunity: Critical Path to product discovery, development and medical use. Washington DC. October, 2005. (Organizer and co-chair)
- Integrative Neural Immune Program, Biodefense Workshop 2007. (Organizing Committee)
- Scientific Steering Committee for Bacterial Therapeutics at USAMRIID. Member, 2002-2004.
- CDER/CBER Biotechnology GTWG group. Member.
- · Committee for Advanced Scientific Education. Member.
- The Interagency Coordinating Committee on the Validation of Alternative Methods. Consult.
- Ad hoc scientific reviewer for: Journal of Immunology, Trends in Immunology, Cellular Immunology, Journal of Leukocyte Biology, Cellular immunology, Life Sciences, Journal of Endotoxin Research, Endocrinology, Virology and Clinica Chimica Acta, Oligonucleotides, Biomacromolecules.
- AD hoc grant reviewer for study sections at NCI, NCCAM, NIST, USAMRIID, and FDA's Office of Women's Health.

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Patents:

- Verthelyi, D., Grajkowski, A., Beaucage, S.L. CpG Oligonucleotide Prodrugs, Compositions Thereof and Associated Therapeutic Methods. U.S. Provisional Patent Application 60/635,744 – 12/13/04. International Patent Application PCT/US2005/044935 – 12/13/05.
- Method of preventing infections from bioterrorism agents with immunostimulatory CpG oligodeoxynucleotides. Application no. 60/422,964 filed on November 2002. Inventors: Dennis Klinman, Daniela Verthelyi and Bruce Ivins.
- Method for rapid generation of mature dendritic cells. Inventors: Filed August 2001. Inventors: Mayda Gursel, Daniela Verthelyi and Dennis Klinman. E-214-01/0 filed Aug 14 2001. Class: 435372000 (USPTO), C12N005/08 (Intl Class)
- Method of treating secondary infections in HIV-infected subjects with immunostimulatory CpG oligonucleotides. Filed September 2002. Inventors: Daniela Verthelyi and Dennis Klinman.
- Suppressor CpG oligodinucleotides and methods of use. Filed September 24, 2001 and August 1, 2002: 131651. Inventors: Rainald Zeuner, Daniela Verthelyi and Dennis Klinman. Application #60/324,484 and 60/400,826 Class: 514044000 (USPTO), A61K048/00 (Intl Class).
- Oligodeoxynucleotides and their use to induce an immune response. Filed on April 12, 1999, under the Serial number 60/128,898. Inventors: Dennis Klinman. Daniela Verthelvi. and Ken Ishii.

Bibliography:

Peer-reviewed primary research publications

- S. Ansar Ahmed and D. Verthelyi. Antibodies to cardiolipin in normal C57BL/6J mice: Induction by estrogen but not by dihydrotestosterone. (1993) J. Autoimmunity 6, 265-279.
- S. Ansar Ahmed, J. Boone and D. Verthelyi. Anticardiolipin antibodies in autoimmune-prone BXSB and MRLI/Ipr mice, and estrogen-treated normal C57BL/6J mice cross react with other phospholipids. (1993). Int. J. Immunopathol. Pharmacol. 6: 135-147.
- D. Verthelyi and S. Ansar Ahmed. 17β-estradiol but not 5αdihydrotestosterone augment antibodies to double stranded deoxyribonucleic acid in non-autoimmune C57BL/6J mice. (1994). Endocrinology 135: 2615-2622.

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 D. Verthelyi and S. Ansar Ahmed. Characterization of estrogen-induced antibodies to cardiolipin in normal mice. (1997) J. Autoimmunity. 10:115-125.

- D. Verthelyi, N. Dybdal, K. Elias, and D. Klinman. DNAse treatment delays anti-DNA autoantibody production but does not improve survival of lupus prone (NZB x NZW)F; Mice. (1998). Lupus 7:223-230.
- D. Verthelyi and S. Ansar Ahmed. Estrogen increases the number of plasma cells and enhances their autoantibody production in nonautoimmune C57BL/6 mice. (1998). Cell Immunol. 189(2):125-34.
- K.J. Ishii, W.R. Weiss, M. Ichino, D. Verthelyi and D.M. Klinman. Activity and safety of DNA plasmids encoding IL-4 and IFN gamma. (1999) Gene Therapy. 6: 237-244.
- J.C. Davis, S. Manzi, C. Yarboro, J.Rairie, I. McIness, D. Verthelyi, D. Sinicropi, V.G. Hale, H. Austin, D.T. Boumpas, J.H. Klippel. Recombinant human DNASE I in the treatment of lupus nephritis. (1999). Lupus 8 (1): 68 -76.
- D. Verthelyi and D.M. Klinman. Sex hormone levels correlate with the activity of cytokine secreting cells in vivo. (2000) Immunology 10: 384-390.
- D. Verthelyi, M. Petri, M. Ylamus, D.Klinman. Disassociation of sex hormone levels and cytokine production in SLE patients. (2001). Lupus. 10:352-358.
- Nerthelyi, K.J. Ishii, M. Gursel, F. Takeshita and D.M.Klinman. Human peripheral blood cells differentially recognize and respond to two distinct CpG motifs. (2001). J.Immunol. 166: 2372.
- S. Kamstrup, D. Verthelyi and D. Klinman. Response of porcine monocytes to CpG-containing oligodeoxynucleotides. (2001) Vet. Micobiol. 78:353-362.
- D. Verthelyi, R. T. Kenney, R.A. Seder, and D. Klinman. CpG Oligodeoxynucleotides as vaccine adjuvants in Primates. (2002). J. Immunol. 168(4): 1659-1663.
- 14. M. Gursel, D. Verthelyi, I. Gursel, K. Ishii, and D. M. Klinman. Differential and competitive activation of human immune cells by distinct classes of CpG oligodeoxynucleotide. (2002). J Leukoc Biol. 71(5):813-20.

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 R.A. Zeuner, D.M. Klinman, K. Ishii and D. Verthelyi. Prevention of inflammatory arthritis by "Suppressive" Oligodeoxynucleotides. (2002). Arthritis Rheum. 46:2219-2224.

- M. Gursel, D. Verthelyi and D.M. Klinman. CpG oligodeoxynucleotides induce human monocytes to mature functional dendritic cells. (2002). European Journal of Immunol. 32: 2617-2622.
- R. A. Zeuner, D. M. Klinman, G. Illei, C. Yarboro, K. J. Ishii, M.Gursel, D. Verthelyi. Response of PBMC from Lupus Patients to Stimulation by CpG Oligodeoxynucleotides. (2003). Rheumatology 42(4):563-569.
- C. A. Leifer, D. Verthelyi, D.M. Klinman. Heterogeneity in the Human Response to Immunostimulatory CpG Oligodeoxynucleotides. (2003) Journal of Immunotherapy 26(4) 313-319
- N. Verthelyi, M. Gursel, R. Kenney, J. Lifson, S. Liu, J. Mican, and D. M. Klinman. CpG Oligodeoxynucleotides Protect Normal and SIV-Infected Macaques From Opportunistic Infection. (2003). J. Immunol. 170:4717-4723.
- R. A. Zeuner, D. Verthelyi, M. Gursel, K.J. Ishii and D.M. Klinman. Influence of stimulatory and suppressive DNA motifs on host susceptibility to inflammatory arthritis. (2003). Arthritis and Rheum. 48(6): 1701-1707.
- S. Mendez, K. Tabbara, Y. Belkaid, S. Bertholet, D. Verthelyi, D. Klinman, R. A. Seder and D. L. Sacks. Live vaccination against cutaneous leishmaniasis attenuated by co-injection of CpG-ODN. (2003) Infection and Immunity 71(9):5121-5129.
- D. Verthelyi, V. W. Wang, J. D. Lifson and D. M. Klinman. CpG oligodeoxynucleotides improve the response to hepatitis B immunization in healthy and SIV infected rhesus macaques. (2004). AIDS 30; 18(7):1003-1008.
- B. Flynn, V. Wang, D. L. Sacks, R. A. Seder and D. Verthelyi. Prevention and treatment of cutaneous leishmaniasis in primates using type D CpG ODN. (2005). Infection and Immunity. 73(8):4948-4954.
- A. Grajkowski*, J. Pedras-Vasconcelos*, V.W. Wang, C. Ausín, S. Hess, D. Verthelyi, and S. L. Beaucage. Thermolytic CpG-containing DNA oligonucleotides as potential immunotherapeutic prodrugs. (2005). Nucleic Acid Research. 21: 33(11): 3550-3560.

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J. Pedras-Vasconcelos, D. Goucher, L. Tonelli, V. W. Wang, S. Ito, and D. Verthelyi. CpG ODN protect newborn mice from a lethal challenge with the neurotropic Tacaribe arenavirus. (2006) J. Immunol. 176:4940-4949.

- 26. M. Puig, A. Grajkowski, M. Boczkowska, C. Ausín, S. L. Beaucage, and D. Verthelyi. Use of thermolytic formyl protective groups to prevent G-tetrad formation in CpG ODN type D: structural studies and immunomodulatory activity in primates. (2006). Nucleic Acid Research. 34 (22):6488-6495.
- 27. E.D. Ponomarev, E.J. Kerschen, L.P. Shriver, S.H. Burnett, J. Pedras-Vasconcelos, D Verthelyi, A.M. Kaplan, D.A. Cohen and B.N. Dittel. GM-CSF Production by Autoreactive T Cells is Required for the Activation of Microglial Cells and the Onset of Experimental Autoimmune Encephalomyelitis. (2007) J. Immunol. 178 (1):39048.
- N. Katsenelson, S. Kanswal, M. Puig, D. Verthelyi, and M. Akkoyunlu. Synthetic CpG deoxyoligonucleotides upregulate the expression of BAFF receptors on B lymphocytes and augment BAFF and APRIL mediated immunoglobulin secretion. (2007). European Journal of Immunology. 37(7):1785-95.
- C. Sauder, J Pedras-vasconcelos, M. Puig and D. Verthelyi. The IP10 (CXCL10) specific cDNA probe of the mCK-5c multiprobe RNase protection assay kit carries two nucleotide insertions that complicate the interpretation of results. (2008). Cytokine in press.
- J. A. Pedras-Vasconcelos, M. Puig, C. Sauder, C.Wolbert, M. Ovanesov, D. Goucher and D.Verthelyi. Anti-TNFα therapy rescues neonatal mice from lethal Arenavirus -induced meningoencephalitis. J.Immunol. Submitted.

Review articles and book chapters:

- D. Verthelyi and Klinman D.M. Impact of the type 1: type 2 cytosine imbalance on disease activity in SLE. In: Lupus-Cellular and Molecular Pathogenesis. Eds: Kammer GM and Tsokos GC, Humana Press, Totowa NJ. pp361-370.
- D.M. Klinman, K.J. Ishii, D. Verthelyi. CpG DNA augments the immunogenicity of plasmid DNA vaccines. (1999) Current Topics Micro. Immunol. 247:131-142.
- 3. D.M. Klinman, **D. Verthelyi**, F. Takeshita and K.J. Ishii. Immune Recognition of Foreign DNA: A Cure for Bioterrorism? (1999). *Immunity*. 11:11-12.
- S. Ansar Ahmed, B.D.Hissong, D. Verthelyi, K. Donner, K. Becker, E. Karpuzoglu-Sahin. Gender and Risk of Autoimmune Diseases: Possible

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- D.M. Klinman, S. Kamstrup, D. Verthelyi, I. Gursel, K.J. Ishii, F. Takeshita and M. Gursel. Activation of the innate immune system by CpG oligodeoxynucleotides: applications and safety issues. (2000). Springer Seminars in Immunopathology. 22: 173-183.
- D. Verthelyi. Sex hormones as immunomodulators in health and disease. (2001), International Immunopharmacology 1 (6): 983-993.
- D.M. Klinman, F. Takeshita, I. Gursel, C.A. Leifer, K.J. Ishii, D. Verthelyi and M. Gursel. CpG DNA: recognition by activation of monocytes. (2002) Microbes and Infection 4(9):897-901.
- D. Verthelyi and D.M. Klinman. CpG ODN: Safety considerations. In: Microbial DNA and Immune Modulation. E.Raz, Ed. Humana Press, CA. p385-396 (2002).
- D. Verthelyi and D.M. Klinman. Immunoregulatory activity of CpG oligonucleotides in humans and non-human primates. (2003). Clinical Immunology109 (1): 64-71.
- D. Verthelyi. Sex hormones and the immune system. In: Encyclopedia of Hormones. H.L. Henry and A.W. Norman, Eds. Academic Press. (2003).
- 11. D. Verthelyi and R.A. Zeuner. CpG DNA signaling in dendritic cells and B cells: Not just TLR9. (2003). Trends in Immunology 24 (10):519-522.
- D.M. Klinman, D. Currie, I. Gursel, D. Verthelyi. Use of CpG oligodeoxynucleotides as immune adjuvants. (2004). *Immunol Rev.* 199:201-16.
- A. Grajkowski, J. Pedras-Vasconcelos, C. Ausín, D. Verthelyi, and S.L. Beaucage. Design and development of thermolytic DNA oligonucleotide prodrugs. 2005. New York Academy of Science. 1058:26-39.
- D. Verthelyi. Adjuvant properties of CpG oligonucleotides in primates. 2006.
 In: DNA Vaccines. Mark Saltzman, ed. Methods Molec. Med. 127:139-158.
- D. Verthelyi. Female's heightened immune status: Estrogen, T cells and iNOS in the balance. 2006. Endocrinology. 147:659-661.
- J. Wang, J. Lozier, G. Johnson, S. Kirshner, D. Verthelyi, A. Pariser, E. Shores, and A. Rosenberg Neutralizing Antibodies to Therapeutic Enzymes: Prediction, Prevention, and Treatment. Submitted.

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 D. Verthelyi and Montserrat Puig. Structure/function of IFNα-inducing CpG ODN. In press.

Selected scientific presentations at national and international meetings:

- FDA perspective on pre-screening protein therapeutics. Immunogenicity for Biotherapeutics. McLean. Virginia. May.2008. Invited speaker.
- Re-tooling innate and inflammatory responses to treat viral encephalitis. Blood Research Institute, Milwakee, Wisconsin. April 2008. Invited seminar.
- Oligonucleotides for Infectious Diseases, an Overview. Oligonucleotide-based therapeutics. DIA/FDA/Health Canada/OTS. Bethesda, April 19-20, 2007 Invited Speaker and Session Chair.
- TLR9: Targeting the immune system for immunoprotection. Boston University Medical School. September, 2006.
- Thermolytic oligodeoxynucleotides: a new target for TLR-9. Recent Advances in pattern recognition-Toll 2006. Salvador, Brazil. March, 2006.
- TLR9 agonists in immunoprotection and vaccine development. National Academy of Medicine. Argentina. March 2006.
- Meningoencephalitis in Tacaribe-infected Mice: The Role of the Immune Response". DVP Seminar Series, CBER, FDA. Lecture. January, 2006.
- Toll Receptors and immunoprotection. Medical Countermeasures and Innate Immunity: Critical Path to Product Discovery, Development and Medical Use. Fort McNair. Washington DC. December 8, 2005. Chair and Speaker.
- TLR-9: Targeting the innate immune system for immunoprotection. NIH Research Festival. Lecture. October, 2005.
- 10. Targeting DC for immunoprotection and vaccine development: A new generation of CpG ODN type D. 2nd International Conference
- Dendritic Cells at the Host-Pathogen Interface. Warrenton, Virginia. September 2005.
- Immune Targeting using Toll Like Receptor (TLR) Agonists. CDER Scientific Rounds. June 2005. Rockville, Maryland. Lecture.
- CpG protects neonatal mice against a lethal New World Arenavirus Infection. Keystone Symposia: Innate immunity to pathogens. January, 2005. Seamboat, CO.
- 14. Art and science behind immunogenicity testing: The FDA perspective. Speaker. 17th Annual DIA EuroMeeting - Medicines in Changing Times. March, 2005. Lisbon. Portugal. Invited speaker.
- Distinct immunoprotective and adjuvant effect of TLR ligands in primates. Keystone Symposia: Innate immunity to pathogens. January, 2005. Seamboat, CO.
- 16. Targeting the innate immune system for immunoprotection: The primate experience. DTP seminar series. October, 2005. Lecture.
- Thinking about immunogenicity: from Toll receptors to decision making. Barnett's international 3rd Annual meeting on Immunogenicity Testing For Therapeutics. Philadelphia, PA. September 2005. Invited speaker.
- 18 Immune Targeting using Toll Like Receptor (TLR) Agonists. CDER Scientific

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- Rounds. June 2005. Rockville, Maryland. Lecture.
- Selective application of CpG ODN as vaccine adjuvants and immunoprotective agents in healthy and immunocompromised primates. Seminar. CBER Parasitology Interest Group. Lecture. April, 2004.
- CpG ODN protects newborn mice against lethal infection with Tacaribe, a prototypic New World arenavirus. FDA Science Forum 2004.
- 21. Safety and efficacy of CpG ODN as vaccine adjuvants and immunoprotective agents in healthy and immunocompromised subjects. FDA Science Forum 2004.
- CpG ODN as vaccine adjuvants and immunoprotective agents in healthy and immunocompromised SIV-infected primates. FASEB, Washington DC. April, 2004.
- 23. CpG-induced protection in newborn mice against a lethal New World Arena virus infection. FASEB, Washington DC. April, 2004.
- Gender and sex hormones in response to immunostimulatory CpG Oligodeoxynucleotides. Speaker. American Society of Reproductive Immunology, Yale, New Haven, CT Lecture. June, 2003.
- 25. CpG ODN act as vaccine adjuvants and immunoprotective agents in healthy and immunocompromised primates. Workshop. Keystone Conference: Linking Innate and Adaptive Immunity. Taos, NM, January, 2003.
- Immunoprotection using CpG ODN in healthy and immunocompromised primates. Speaker. Minisymposium on Cytokines and Innate Immunity. Frederick. MD. September 26, 2002.
- 27. CpG oligodeoxynucleotides indirectly stimulate the maturation of human monocytes into functional dendritic cells. Dendritic Cells At The Host Pathogen Interface. Warrenton, VA may 4-7, 2002.
- CpG oligodeoxynucleotide induced tumor lysis in short term transitional cell carcinoma cultures: a pilot study. 49th Annual James C. Kimbrough Urological Seminar. July 2002.
- Two distinct CpG DNA Sequences Differentially Stimulate an Innate Immune Response by Human PBMCs. 2001 FDA science forum Washington, DC February 15-16, 2001.
- Novel CpG oligonucleotides act as vaccine adjuvants in primates. Speaker. 2nd International Symposium "Activating Immunity with CpG Oligos. Florida. October, 2001.
- Two distinct CpG DNA Sequences Differentially Stimulate the Human Innate Immune System. FDA Forum on Regulatory Sciences. Washington DC. February. 2001.
- Characterization of distinct CpG DNA sequences that stimulate the human immune system. Keystone symposia: Interface between innate and adaptive immunity. Keystone, January, 2001.
- Characterization of distinct types of immunostimulatory CpG DNA motifs. Seminar. USDA. Beltsville. MD. April. 2000.
- 34. Regulation of Immunity and Autoimmunity. Keystone, January, 2001
- 35. Potential contributions of CpG oligonucleotides to autoimmunity. Cytokines in Tolerance, Autoimmunity and Inflammation. Speaker. Bethesda MD, January,

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2000.

Characterization of DNA motifs that are immunostimulatory for human PBMC.
 Speaker. Millennium Conference on Nucleic Acid Therapeutics. Clearwater FL.
 January 2000.

- Assessing ex-vivo antibody and cytokine secretion using ELIspot. Seminar. Eye Institute. N.I.H April 22, 1999.
- Relative potency of immunostimulatory DNA motifs in humans. Keystone symposia: DNA Vaccines: Immune Responses, mechanisms and manipulating antitien processing. Snowbird, Utah. April, 1999.
- 39. Cytokine abnormalities in systemic lupus erythematosus: Do sex hormones play a role? Linking environmental agents to autoimmune diseases. National Institute of Environmental Health Sciences (NIEHS). September 1-3, 1998.
- Evaluation of DNase treatment in murine lupus. Workshop. 1997 FDA Forum on Regulatory Sciences. Washington DC. December 1997.
- Contribution of sex hormones to cytokine abnormalities characteristic of SLE. FASEB Summer Research Conference on Autoimmunity. Saxton River, VT. June. 1997.
- 42. DNAse treatment of DNA-anti-DNA immune complexes in SLE. Rheumatoid Arthritis: Experimental therapies, Orlando, October, 1996.
- 43. Estrogen alters B cell functions and apoptosis. Sixth annual meeting, American Society for Reproductive Immunology. Knoxville TN. June, 1996.
- 44. Estrogen induces autoimmunity in non-autoimmune C57BL/6J mice. Ninth International Congress of Immunology. San Francisco. July 23-29, 1995.
- Estrogen induces anti-cardiolipin antibodies in normal C57BL/6J mice. Sixth International Symposium on anti-phospholipid antibodies. Leuven, Belgium. 14-17 September. 1994.